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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/601,300      | 06/18/2003  | Mark J. Clifford     | RUBI5850            | 5880             |

22430 7590 12/29/2005  
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EXAMINER

FOREMAN, JONATHAN M

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3736

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                 |                                 |  |
|------------------------------|---------------------------------|---------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/601,300   | Applicant(s)<br>CLIFFORD ET AL. |  |
|                              | Examiner<br>Jonathan ML Foreman | Art Unit<br>3736                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-10, 14-17, 19-21, 25, 26 and 29-49 is/are pending in the application.  
 4a) Of the above claim(s) 32-49 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-4, 8-10, 14-17, 19-21, 25, 26 and 29-31 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/29/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed 9/29/05 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits. However, Albrecht et al., Burbank et al. and Lee et al. have already been made of record (See Office Action mailed 3/24/05).

### ***Specification***

1. The disclosure is objected to because of the following informalities: Page 35, line 23 states "Fig. 154".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 - 4, 8 - 10, 14 - 17, 19 - 21, 25, 26 and 29 - 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In regards to claims 1 and 16, the specification fails to describe how the specimen collection assembly is disposed along the shaft and away from the distal end thereof. To the contrary, the disclosure teaches the specimen collection assembly being near the distal end (Page 9, line 4; line 18). In addition, claims 1 and 16 stated that the specimen collection assembly was disposed near the distal end prior to the amendment filed 9/29/05. Furthermore,

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claim 8 states that the specimen collection assembly is attached to the distal end of the shaft. Claims 1 and 16 now include limitations relating to the specimen collection assembly being configured to collect the specimen non-circumferentially along the shaft. However, the specification fails to include such a disclosure. To the contrary, the specification teaches collecting the specimen along an outer circumference of the shaft as it is rotated (Page 20, line 17 – Page 21, line 15; Page, 34, lines 10 – 21).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 - 4, 8 - 10, 14 - 17, 19 - 21, 25, 26 and 29 - 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claims 1 and 16, it is unclear what is meant by “non-circumferentially along the shaft”. For the purposes of this Office Action, it has been considered by the Examiner to relate to a sample smaller than the entire circumference of the shaft.

In regards to claims 8 and 14, it is unclear how the flexible membrane can be attached to the distal end of the shaft when the flexible membrane (i.e. specimen collection assembly) is disposed away from the distal end of the shaft.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent

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by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1 – 4, 9, 10, 16, 17, 19 – 21, 25, 26 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,242,663 to Cano.

In regards to claims 1 – 4, 9, 10, 16, 17, 19 – 21, 25, 26 and 26, Cano discloses a device for collecting a tissue specimen including a shaft (8) defining a proximal end and a distal end; a specimen collection assembly (Col. 4, lines 42 – 45) disposed along the shaft and away from the distal end, the specimen collection assembly including a flexible membrane (16; Col. 5, lines 36 – 41) configured to collect the specimen non-circumferentially (Figure 6) along the shaft; a specimen management assembly (12, 14), the specimen management assembly being disposed partially within the shaft (Col. 6, lines 27 – 28) and away from the distal end thereof (Figure 7), the specimen management assembly being coupled to and configured to act upon the specimen collection assembly to draw the specimen collected in the flexible membrane toward the proximal end of the shaft (Col. 6, lines 24 – 29). The flexible membrane is configured to isolate (Col. 6, lines 17 – 19) the collected specimen from a mass of tissue surrounding the specimen. The specimen management assembly is coupled to the flexible membrane. The specimen management assembly is configured to selectively pull on the flexible membrane toward the proximal end of the shaft (Col. 6, lines 24 – 29). The specimen management assembly includes at least one wire (Col. 5, line 25; lines 41 – 45) coupled to the flexible membrane. The at least one wire is configured to selectively pull on the flexible membrane toward the proximal end of the shaft (Col. 6, lines 24 – 29).

8. Claims 1 - 4, 8 - 10, 14 - 17, 19 - 21, 25, 26 and 29 - 31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,508,773 to Burbank et al.

In regards to claims 1 - 4, 8 - 10, 14 - 17, 19 - 21, 25, 26 and 29 - 31, Burbank et al. discloses a device for collecting a tissue specimen including a shaft (34) defining a proximal end and a distal end; a specimen collection assembly disposed along the shaft and away from the distal end (Figure 8), the specimen collection assembly including a flexible membrane (14) configured to collect the specimen non-circumferentially along the shaft (Col. 21, lines 5 – 12; lines 20 – 24); a specimen management assembly (32, 48, 56), the specimen management assembly being coupled to the specimen collection assembly being disposed partially within the shaft (34) and away from the distal end thereof and being coupled to and configured to draw the specimen collected in the flexible membrane toward the proximal end of the shaft (Col. 13, lines 13 – 40) in that as the membrane is tightened, the specimen will spread out as it is being compacted. The flexible membrane is configured to isolate the collected specimen from a mass of tissue surrounding the specimen. The specimen management assembly is coupled to the flexible membrane. In the embodiment described by figures 11a – 11d, Burbank et al. discloses the specimen management assembly being configured to selectively pull on the flexible membrane toward the proximal end of the shaft (Col. 14, lines 59 – 64). A portion of the flexible membrane is attached to the distal end of the shaft. The specimen management assembly includes at least one wire (48, 56) coupled to the flexible membrane. The device includes a specimen cutting assembly (88) configured to cut the specimen from a mass of tissue.

### ***Response to Arguments***

9. Applicant's arguments filed 9/29/05 have been fully considered but they are not persuasive. Applicant asserts that Burbank et al. fails to disclose a device configured to collect a specimen non-circumferentially along the shaft; having a specimen management assembly disposed partially within the shaft or being away from the distal end of the shaft; or drawing the specimen toward the

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proximal end of the shaft. However, the Examiner disagrees. The device as disclosed by Burbank et al. is configured to collect a specimen non-circumferentially along the shaft (Col. 11, line 45 – Col. 12, line 25; Col. 21, lines 5 – 12; lines 20 – 24). A recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus that differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1947); *In re Yanush*, 477 F.2d 958, 177 USPQ705 (CCPA 1973); *In re Finsterwalder*, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); *Ex parte Masham*, 2 USPQ2d 1647 (BbPatApp & Inter 1987). In the present case, the device as disclosed by Burbank et al. is fully capable of collecting a specimen non-circumferentially in that each of the sheath deployment members (48) are separately actuatable and the device need not be rotated completely around to sever tissue. The specimen management assembly (32, 48, 56) is disposed partially within the shaft (34) and away from the distal end thereof (Figure 9). As the membrane is tightened, the specimen will spread out as it is being compacted, including proximally.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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